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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HANS-URICH PETEREIT, THOMAS BECKERT,
MANFRED ASSMUS, WERNER HOESS, WOLFGANG FUCHS, and
HARTMUT SCHIKOWSKI

Appeal 2007-4001¹
Application 09/913,720
Technology Center 1600

Decided: February 19, 2008

Before DONALD E. ADAMS, LORA M. GREEN, and
RICHARD M. LEOVITZ, *Administrative Patent Judges*.

LEOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 1-8, 10,
and 11. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

¹ Heard January 22, 2008.

The claims are directed to a process of molding thermoplastics suitable for carrying active pharmaceutical ingredients, such as capsules (Spec. 1-2). The method involves melting a copolymer mixture comprising a mold-release agent, and devolatilizing the mixture prior to injecting it into a mold cavity (Spec. 2-3).

Appellants request review of the following rejection:

Claims 1-8, 10, and 11 under 35 U.S.C. § 103(a) as obvious over Lehmann (U.S. Pat. No. 5,705,189, Jan. 6, 1998) in combination with Vetter (U.S. Pat. No. 5,548,033, Aug. 20, 1996) (Answer 3).

Claims 1 and 3, which are representative of the claimed subject matter, read as follows:

1. An injection moulding process comprising:

A) Melting a mixture comprising

a) a (meth)acrylate copolymer comprising from 40 to 100% by weight of free-radical-polymerized C₁-C₄-alkyl esters of acrylic or methacrylic acid and from 0 to 60% by weight of (meth)acrylate monomers having an anionic group in the alkyl radical, and

b) from 0.1 to 3% by weight of a release agent,
and, optionally,

c) from 0 to 50% by weight of a drier,

d) from 0 to 30% by weight of a plasticizer,

e) from 0 to 100% by weight of additives or
auxiliaries,

f) from 0 to 100% by weight of an active
pharmaceutical ingredient,

g) from 0 to 20% by weight of another polymer or
copolymer,

wherein the amounts given for components b) to g) are
based on the (meth)acrylate copolymer a), and wherein

the mixture prior to melting has a content of more than
0.5% by weight of low-boiling constituents with vapour
pressure of at least 1.9 bar at 120°C,

B) Devolatilizing the mixture in the thermoplastic state at a temperature of at least 120°C, thereby lowering to not more than 0.5% by weight the content of the low-boiling constituents with vapour pressure of at least 1.9 bar at 120°C,

C) Injecting the molten and devolatilized mixture into the mould cavity of an injection mould, the temperature of the mould cavity being below the glass transition temperature of the (meth)acrylate copolymer by at least 10°C, cooling the molten mixture, and removing the resultant moulding from the mould.

3. The process according to Claim 1, wherein the (meth)acrylate copolymer comprises, as (meth)acrylate monomer having an anionic group in the alkyl radical, from 1 to 50% by weight of methacrylic acid.

ISSUES ON APPEAL

The Examiner finds that Lehmann teaches steps A) and C) of claim 1, but does not describe “B) Devolatilizing the mixture in the thermoplastic state” as recited in the claim. However, the Examiner finds that Vetter describes this step in a thermoplastic molding process, and contends that it would have been obvious to have modified Lehmann’s process with Vetter’s teaching.

Appellants contend that there would have been no motivation to incorporate Vetter’s devolatilization step into Lehmann. They also assert they have evidence of superior results.

Thus, the issues in this appeal are: 1) whether the Examiner erred in finding it obvious to have combined the teachings of Lehmann and Vetter; and 2) whether Appellants evidence of “superior results” rebuts the Examiner’s case of prima facie obviousness.

FINDINGS OF FACT (“FF”)

In making an obviousness determination, it is necessary to take the following factors into consideration: (a) the scope and contents of the prior art; (b) the differences between the prior art and the claimed invention; (c) the level of skill in the pertinent art; and (d) evidence of secondary considerations. *Graham v. John Deere*, 383 U.S. 1, 17 (1966). We begin with the scope and contents of the prior art.

The Lehmann Patent

1. Lehmann describes a thermoplastic material comprising copolymers of acrylic or methacrylic acid, methyl acrylate, alkyl esters of acrylic and/or methacrylic acid (Lehmann, at col. 2, ll. 54-61; at col. 3, ll. 51-61; Answer 3) useful for pharmaceutical uses, such as drug coatings (Lehmann, at col. 1, ll. 5-13 and 60-67).
2. The thermoplastic material can be mixed with auxiliaries, such as plasticizers, fillers, and mold-release agents (Lehmann, at col. 3, l. 62 to col. 4, l. 2; Answer 3).
3. Examples 2, 3, and 5 comprise a mold-release agent (glycerol monostearate) in the amount of 2 wt %; Example 4 contains 1 wt % mold-release agent (Lehmann, at col. 4, ll. 63-66).
4. The polymerization of the monomers to produce the copolymer is achieved according “to the usual methods of radical polymerization.” (Lehmann, at col. 3, ll. 37-50).
5. The thermoplastic material is formed by melting the copolymers, along with auxiliaries, at temperatures of 120° to 180°C, and then injecting the melt into molds (Lehmann, at col. 2, l. 66 to col. 3, l. 7; at col. 4, ll. 3-6).

6. The melts can also be formed into films by extrusion (Lehmann, at col. 3, ll. 10-20; Answer 4-5).

The Vetter Patent

7. Vetter describes a method of processing thermoplastic melts in which a degassing extruder is utilized to devolatilize the melt (Vetter, at col. 5, ll. 13-48; Answer 3).

8. The devolatilization step is used to remove impurities, such as treatment agents, secondary products, and residual monomers which can lead to turbidity or corrosion, and “can be applied to many different treatment processes” (Vetter, at col. 2, ll. 20-60; at col. 3, ll. 17-39; Answer 4).

9. “A successful method of reducing the content of residual monomers in the melt provides for the incorporation of a small quantity of water into the melt. During the subsequent devolatilisation, the water evaporates and carries off the monomer vapors” (Vetter, at col. 2, ll. 39-44; Answer 5).

10. Suitable polymers for Vetter’s method include methacrylic acid, acrylic acid, copolymers of methacrylate esters with acrylate esters, and poly(methyl methacrylate) (Vetter, at col. 5, l. 49 to col. 5, l. 6; Answer 3).

Differences between the prior art and the claimed invention

Once the scope and content of the prior art has been established, the next step is to ascertain the differences between the prior art and the claimed invention. *Graham*, 383 U.S. at 17. The following numbered findings of fact are relevant to this determination:

11. Claim 1 is directed to an injection moulding process comprising:

12. A) melting a thermoplastic mixture comprising a (meth)acrylate copolymer, comprising “esters of acrylic or methacrylic acid” and “from 0.1 to 3% by weight” of a mold release agent;

13. B) devolatilizing the mixture; and

14. C) “[i]njecting the molten and devolatilized mixture into the mould cavity.”

15. Lehmann describes copolymers of acrylic or methacrylic acid, methyl acrylate, alkyl esters of acrylic and/or methacrylic acid (FF 1; Lehmann, at col. 2, ll. 54-61; at col. 3, ll. 51-61; Answer 3) that meet the limitations of the (meth)acrylate copolymer of claim 1 (FF 12; Answer 7).

16. Lehmann also teaches that the copolymer can contain a mold release agent, and provides examples in which it is present in the amount of 1 and 2 wt % (FF 2, 3; Lehmann, at col. 3, l. 37 to col. 4, l. 2) – which fall within the claimed range of from 0.1 to 3% by weight of a mold release agent (FF 12).

17. The copolymer in Lehmann’s process is melted and injected into molds (FF 5; Lehmann, at col. 2, l. 66 to col. 3, l. 7; at col. 4, ll. 3-6) as in steps A) and C) of the claimed process (FF 11, 12, 14).

18. Lehmann does not teach that the copolymer melt is devolatilized as required by step B) of the claimed process (Answer 3).

19. However, Vetter teaches devolatilizing a thermoplastic melt (FF 7, 8) as in step B) of the claimed process.

Reason to combine the prior art

The next step after ascertaining the differences between the prior art and the claimed invention is to identify a reason why persons of ordinary skill in the art would have been prompted to combine the prior art to have made the claimed invention. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). The following findings of fact are relevant to this issue:

20. Vetter states that devolatilizing a thermoplastic melt is useful to remove impurities, such as treatment agents, secondary products, and residual monomers, leading to a better product (FF 8; Vetter, at col. 2, ll. 20-60; at col. 3, ll. 17-39; Answer 4).

21. Persons of ordinary skill in the art would have had reason to utilize Vetter's devolatilization step in Lehmann's method for its expected benefit in removing impurities, such as the residual monomers which occur in copolymer mixtures² (FF 8, 9; Answer 4).

22. The ordinary skilled artisan would have desired to remove impurities from Lehmann's thermoplastic material because the latter teaches it for pharmaceutical use (FF 1) and it is well known that pharmaceutical compositions must be substantially free of impurities because they are intended for human use.

23. Vetter's copolymers comprising methacrylic acid, acrylic acid, copolymers of methacrylate esters with acrylate esters, or poly(methyl methacrylate), which are described as suitable for its process (FF 10; Vetter, at col. 5, l. 49 to col. 5, l. 6; Answer 3), are similar to those which are

² Oral Hearing Transcript 8: 20-24 ("JUDGE GREEN: Very few reactions go to 100 percent. So even though Lehmann does not expressly say there are leftover monomers, I think one of ordinary skill in the art would understand, more likely than not, there are leftover. MR. DOUGHTY: I agree with that and –").

claimed and described in Lehmann (FF 1; Lehmann, at col. 2, ll. 54-61; at col. 3, ll. 51-61; Answer 3).

24. Because of the similarities in the copolymers disclosed by Vetter and Lehmann (FF 23), as well as Vetter's teaching that its method "can be applied to many different treatment processes" (FF 8), the ordinary skilled artisan would have expected devolatilization to benefit Lehmann's process.

ANALYSIS

The Examiner has the burden of establishing prima facie obviousness of the claimed invention. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Once a prima facie case has been established, the burden shifts to Applicant to provide rebuttal arguments or evidence. *Hyatt v. Dudas*, 492 F.3d 1365, 1369-70 (Fed. Cir. 2007).

In this case, we conclude there is adequate evidence of record to establish prima facie obviousness of the claimed subject matter. The evidence shows that Lehmann describes a method of producing drug coatings which involves melting a thermoplastic mixture comprising a copolymer and mold release agent as in step A) of claim 1, and injecting the mixture into a mold – as recited in step C) of the claim (FF 14-17). While Lehmann does not teach devolatilizing the mixture as in step B) of claim 1 (FF 18), Vetter teaches such a step (FF 7, 8, 19), and persons of ordinary skill in the art would have had reason to have applied it to Lehmann's process (FF 21-22). Thus, we turn to Appellants' rebuttal arguments and evidence.

Appellants argue that Vetter "is not directed to the devolatilization of untreated poly(methyl methacrylate) polymer, as is the case with the

copolymer of the present claims” (App. Br. 4). It “is clear from the claims that there is no formation” of “a reaction product like that described in Vetter” (Reply. Br. 2).

We do not find this argument persuasive. Vetter describes devolatilization as useful to remove impurities, including treatment agents, secondary products, and residual monomers (FF 7; Vetter, at col. 3, ll. 17-39; at col. 2, ll. 20-50; Answer 4). Thus, even were no treatment agent utilized in the polymerization process that would result in a “reaction product,” persons of ordinary skill in the art would still have had reason to have used devolatilization to remove residual monomers or secondary products from it (*id.*).

Appellants also argue that there is no motivation to have combined Lehmann and Vetter because

the positive addition of water in Vetter et al is different from the situation in the present invention in which low boiling constituents of the mixture of the present claims and devolatilization thereof is discussed on pages 11 and 12 of the specification. It is stated therein that the low boiling constituents in the copolymer of the present claims are limited to mainly water absorbed from the moisture present in air or derived from the polymer preparation process. There is no positive addition of water to the composition of the present claims. Although the Examiner argues that the present claims do not exclude the positive addition of water to the process, the present specification on pages 11 and 12 clearly teaches away from the positive addition of water to the mixture used in the process of the present claims

(App. Br. 4).

We are not persuaded by this argument that the Examiner erred. Based on Vetter’s teaching, persons of ordinary skill would have recognized that the addition of water to a thermoplastic melt would have been beneficial

to remove residual monomers during a devolatilization step (FF 21-22). Claim 1 does exclude the addition of water, and thus is not distinguished over Vetter's method on this basis.

Appellants contend that the Specification teaches away from the addition of water because of the disclosure on pages 11-12 of the Specification. They do not specifically explain why the disclosure in the Specification "clearly teaches away from the positive addition of water to the mixture used in the process of the present claims" (App. Br. 4).

According to the Specification on page 11, "commercially available . . . (meth)acrylate copolymer known per se" contains "low-boiling constituents" which "are mainly water absorbed from the moisture present in air or derived from the polymer preparation process" (Spec. 11). The Specification states that "reduced pressures" during the devolatilization step "lead to more substantial removal of the low-boiling constituents, such as moisture, from the melt" (Spec. 12). Moisture – or water – is mentioned as the main low-boiling constituent – but not the sole low-boiling constituent.

We do not understand how this disclosure teaches away from the addition of water. If water was known to be present in the copolymer, persons of ordinary skill in the art would have recognized that it would not be necessary add additional water – but that the existing water plus the residual monomers would be removed by Vetter's devolatilizing step. Thus, knowledge of this fact would not have led persons of skill in the art against combining Lehmann with Vetter. In fact, it appears that Appellants has added a devolatilization step to the melt process for the same purpose (to remove low-boiling constituents) as taught in the prior art.

On the other hand, if it were not known that water were present in the polymer, persons of skill in the art would have recognized the benefit of adding small amounts of it to facilitate the removal of impurities, such as residual monomers, during devolatilization (FF 21-22). The occurrence of residual monomers in Lehmann's method would have been expected (FF 21, fn. 1).

Appellants also contend that Vetter cannot be combined with Lehmann "because the requirements for the production of injected molded articles in the two references are very different along with the fact that [Vetter] does not teach or suggest a mold release agent" as in claim 1 (App. Br. 5).

This argument is not persuasive. The Examiner has not relied upon Vetter for teaching the release agent, but rather cites Lehmann for the release agent and copolymer of claim 1 (*see* FF 1-4, 15, 16; Answer 3). Appellants have not provided any reason why the presence of a mold-release agent in Lehmann's copolymer would have dissuaded persons of skill in the art from performing a devolatilization step. To the contrary, we find that the similarities between the copolymers of Lehmann and Vetter would have led persons of ordinary skill in the art to have expected devolatilization to benefit Lehmann's process (FF 24).

Obvious can also be rebutted with evidence of unexpected results. Appellants argue that "[s]uperior results are shown for injection moldings produced by the process of the present claims, as compared to injection moldings produced by processes out the present claims" (App. Br. 5).

As evidence, Appellants state that Example 1 in the Specification, which uses a mold release agent in an amount within the claimed range,

“produced no deposits on the surface of the mold used” (*id.*). “In contrast, in Comparative Examiner 2 in which the same monomers were used and the same process” as that in Example 1 “and very close to Examples 1 and 8” of Lehmann, but where the “mold release agent [is] in an amount outside the range of the present claims, . . . matt areas could be found on the surfaces of the capsules produced” (App. Br. 5).

The comparative results are not sufficient to rebut the *prima facie* case of obviousness. As pointed out the by the Examiner (Answer 6), different mold release agents were utilized: stearyl alcohol in Example 1 and glycerol stearate in Comparative Example 2. In addition, the melt temperatures were different (Ans. 6; 180°C versus 160°C). Thus, it is not clear whether the observed differences are a result of the amount of mold agent or the chemical nature of the mold agent, itself. A comparative showing must be sufficient to permit a conclusion respecting the relative differences between the claimed invention and the prior art. *See In re Payne*, 606 F.2d 303, 316 (CCPA 1979). Here, the evidence does not establish that it is the concentration of the mold-release agent which accounts for the superior results, rather than the nature of the agent or the melt temperature. Thus, the evidence is not adequate to rebut the Examiner’s *prima facie* case.

Moreover, we note that Lehmann describes using amounts of a mold release agent which fall within the claimed range (FF 3, 16; Lehmann, at col. 4, ll. 63-66). While Appellants may have recognized an advantage of using a mold release agent within these disclosed range, “[m]ere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention.” *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991). Thus, when the prior art suggests what a patent applicant has

done, any inherent advantages – unless based on unexpected results – cannot form the basis for patentability. *See Ex parte Obiaya*, 227 USPQ 58, 60 (BPAI 1985).

Appellants also compare Example 1 (mold-release agent and devolatilization) to Comparative Example 3 which includes a mold release agent, but no devolatilization step. “The injection molding process of Comparative Example 3 with no devolatilization step produced capsules that had surface defects” (App. Br. 5), but no defects were observed with process in Example 1 (App. Br. 5).

Our problem with this comparison is that Vetter expressly teaches utilizing a devolatilization step to improve the quality of a thermoplastic (FF 8). Thus, the improvement observed in Comparative Example 3 by devolatilizing the melt would have been either expected or an inherent advantage of using a process step suggested by the prior art. The recognition of inherent advantages that result from a process suggested by the prior art does not render nonobvious an otherwise known invention. *See Baxter*, 952 F.2d at 392.

For the foregoing reasons, we affirm the rejection of claim 1. Claims 2, 4-8, 10, and 11 fall with claim 1 because separate reasons for their patentability were not provided. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Claim 3

Claim 3 is directed to the process of claim 1, where “the (meth)acrylate copolymer comprises, as (meth)acrylate monomer having an anionic group in the alkyl radical, from 1 to 50% by weight of methacrylic acid.”

Appellants assert that “the polymer of Claim 3 is an anionic polymer in contrast to the polymers of” Vetter “which are neutral and anionic” (App. Br. 6). They contend that there is no motivation to substitute the polymer of Claim 3 for those of Vetter (*id.*).

This argument is not persuasive. The Examiner has relied upon Lehmann for teaching the claimed polymer (Answer 7). Appellants have not distinguished the polymer in claim 3 from those described in Lehmann. Consequently, we affirm the rejection of claim 3.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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